Information Management Research Applications Development

EDMS RightSite 4.3 Upgrade

Validation Plan

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Completion of this page indicates approval of this document and its content.

# Document Revision History

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# Table of Contents

[INSTRUCTIONS - To update the Table of Contents, click on it and press F9.]

1. Document Approval 2

2. Document Revision History 3

3. Table of Contents 4

4. Acronyms and Definitions 5

5. Overview 6

5.1 Purpose 6

5.2 Scope 6

5.3 Risk Assessment 7

6. System Description 10

6.1 Electronic Document Management System 10

6.2 RightSite Client Application System 10

6.3 Functional Summary 13

7. Validation Planning 14

7.1 Validation Strategy 14

7.2 Roles and Responsibilities 14

7.3 Validation Sequence of Events 16

7.4 Validation Deliverables 16

8. Acceptance Criteria 19

8.1 User Acceptance 19

8.2 Documentation Management 19

# Acronyms and Definitions

| **Acronym/Defined Term** | **Description** |
| --- | --- |
| CFR | Code of Federal Regulations |
| EDMS | Electronic Document Management System |
| FDA | Food and Drug Administration |
| GMP | Good Manufacturing Practices |
| IMOC | Information Management Oversight and Coordination |
| IQ | Installation Qualification |
| IS | Information Services |
| OQ | Operational Qualification |
| PQ | Performance Qualification |
| RIS | Research Information Services |
| QA | Quality Assurance |
| TBD | To be determined |

# Overview

## Purpose

The purpose of this Validation Plan is to provide a systematic approach for the validation of the RightSite 4.3 Upgrade of EDMS effort by:

* Defining the approach and methodology that will be followed for the validation;
* Establishing the specific roles and responsibilities for validation activities;
* Defining the procedure and sequence of events to be followed in the execution of the project;
* Defining the documents to be delivered during the validation effort;
* Serving as the controlling document for the entire RightSite 4.3 Upgrade validation.

The validation will obtain a high degree of confidence that the RightSite upgrade will not adversely affect the EDMS System’s ability to consistently perform according to critical functional requirements and system specifications. Additionally, the validation will establish documented evidence of the first objective, in accord with Company policy and contemporary FDA expectations.

The validation effort will be governed by and in conformance with the following Regulations and Policies:

| **Regulation/Policy** | **Description** |
| --- | --- |
| 21 CFR Part 11 | Electronic Records, Electronic Signatures |
| Administrative Policy 219 | Records Management Program |
| Administrative Policy 409 | Validation of Computer System Applications |
| Administrative Policy 435 | Electronic Records and Electronic Signatures |
| Acme GMP Systems Manual Level II Conformance Standard CS 4-4-1 | Computer Systems Life Cycle Overview |
| Acme GMP Systems Manual Level II Conformance Standard CS 4-4-5 | Computer System Validation Planning |
| Acme GMP Systems Manual Level II Conformance Standard CS 4-4-7 | Computer Systems Testing and Qualification |
| W-AR Policy 314 | Electronic Document Management System (EDMS) and Compliance with Archive Requirements |

## Scope

The scope of this validation is limited to the upgrade of the RightSite interface of the EDMS System. The effort will validate against portions of the EDMS Detail Functional Requirements document applicable to the RightSite interface. As Documentum Administrator and Documentum Intranet Client are installed on top of RightSite, they will need to be upgraded as well. Specifically, the validation will be limited to all requirements listed in the following sections in the requirement document, unless otherwise explicitly stated:

**3. DETAILED FUNCTIONAL REQUIREMENTS**

* 1. Common Functionality
  2. Web Functionality

**4. ADDITIONAL REQUIREMENTS**

* 1. Reporting Requirements
  2. Interfaces with Other Systems
  3. Conversion Requirements
  4. Non-Functional Requirements
  5. Data Requirements
  6. 21 CFR Part 11 Requirements
  7. Security Requirements
  8. Transaction Requirements
  9. Service and Support Requirements
  10. System Administration

## Risk Assessment

A Risk Analysis has been performed to assess any impact on the usability or functionality of the system. As this validation effort is limited to the RightSite interface of the EDMS System, it addresses reasoning for and impact of decisions establishing the scope of the project and deliverables excluded from the effort. The following risks have been identified:

### Adverse Affects on WorkSpace Functionality

*Likelihood of Occurrence:*

It is considered to be very unlikely that the RightSite upgrade project will have any effect on the WorkSpace interface and functionality. Customizations and configurations for the RightSite interface are done on the RightSite server and have no direct impact on WorkSpace. This is an upgrade of only the web interface of the system and should therefore have no affect on WorkSpace.

*Severity of Risk:*

Any effect to WorkSpace would be of medium to low severity. There are other interfaces that could be used in the event of a problem, including RightSite.

*Mitigation of Risk:*

No desktop components are stored on the RightSite server and no RightSite components are stored on the e-Content Server. The IQ portion of the Validation Protocol has specific install steps, none of which affects the e-Content Server or Docbase.

### Content and Data Integrity Corruption

*Likelihood of Occurrence:*

It is considered to be very unlikely that the RightSite upgrade project will affect the content and data integrity of objects within the database. The project applies only to the upgrade of an interface to the overall EDMS System and will involve no changes to the Docbase itself. Customizations will be made to and saved on the separate RightSite servers.

*Severity of Risk:*

Any affect to the content and data integrity of the system would have a severe impact. Many objects in the EDMS System are controlled documents and involve specific security and compliance requirements. Any circumvention of these requirements would have significant compliance ramifications.

*Mitigation of Risk:*

The IQ portion of the Validation Protocol has specific install steps, none of which affects the e-Content Server or Docbase. The OQ portion of the protocol specifically tests access to and security of objects within EDMS and, therefore, indirectly tests that content and data integrity are unaffected.

### System Instability

*Likelihood of Occurrence:*

It is considered to be very unlikely that the RightSite upgrade project will adversely affect the stability of the EDMS System. The project applies only to the upgrade of an interface to the EDMS System. The project involves only a minor version upgrade of the existing software used for the aforementioned interface. Therefore, there is a very slight chance that the interface itself may become unstable.

*Severity of Risk:*

Any affect to the stability of the EDMS System, as a whole, would have major impact. However, as any affect on the stability of the system would most likely be seen in the interface, the severity of the risk is medium to low. There are other interfaces that could be used in the event of a problem, including Documentum WorkSpace.

*Mitigation of Risk:*

The OQ and PQ portions of the Validation Protocol have tests that validate that functional requirements have been satisfied as well as tests that check the performance. Therefore, the stability of the system is indirectly tested in this section, specifically the PQ. System Description

## Electronic Document Management System

EDMS is a multi-functional Docbase, used by nearly every functional group within Acme Research. As a result of this centralization, EDMS contains a large number of distinct object types and custom applications that have been implemented to satisfy a number of unrelated functions across the many functional groups. This is in contrast to a highly specialized, decentralized environment in which each separate department or business function has a distinct Docbase that can be heavily customized to meet the requirements of a distinct group.

EDMS serves as official repository for all submission related documents. The majority of object types (97%) are geared towards regulated content with the primary purpose being marketing application submission, maintenance, or agency correspondence. There are also SOPs in EDMS related to GCP (Clinical), GLP (Drug Safety), and GMP (Chemical Pharmaceutical and Development). The remaining object types (3%) are non-regulated, such as team meeting minutes, captured as part of good business practices and used for knowledge sharing.

## RightSite Client Application System

### General Information

RightSite provides the end-user the ability to access the EDMS System and perform actions on objects within the Docbase via a web browser using Documentum Intranet Client. It also allows the user to perform administrative functions on the system via a web browser using Documentum Administrator or RightSite Server Administrator.

#### Intranet Client

The Documentum Intranet Client application is a dynamic web application. This application physically resides on the same server as of RightSite Server application. The application is categorized into various individual components that perform specific functionality (for example: create new, check in, checkout, view, edit etc.) The application is highly customizable. The architecture of the Intranet Clients is that the clients reside in a read-only product directory, and any customizations you create are placed in a separate custom directory. A central dispatcher determines which forms to use and when.

The high-level process flow is described in the following steps and illustrated in Figure 1:

1. In a web browser, a user requests the start page of the Intranet Client.
2. The browser sends the request to the HTTP server.
3. The HTTP server recognizes the request for an Intranet Client form and passes the request to the RightSite server.
4. RightSite retrieves the form from the file system. The form can contain:

* WebQL tags
* Calls to RightSite built-in and plug-in methods
* Docbasic scripts
* External scripts, such as CGI or Perl

1. The RightSite server processes the WebQL tags, RightSite methods, Docbasic scripts, and external scripts, accessing the Docbase as necessary. This produces a response that consists of HTML and JavaScript.
2. The RightSite server sends the response (HTML + JavaScript) to the HTTP server.
3. The HTTP server sends the response to the user's browser, which processes any JavaScript in the response and renders the HTML.

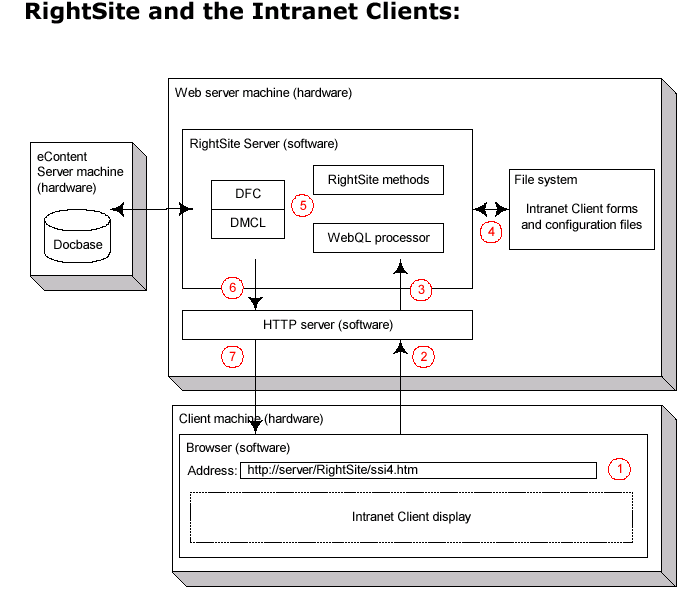


Figure 1 – Intranet Client Process Flow

#### Documentum Administrator

The Documentum Administrator application is a standard web application for users  **http://gvwaprsite01/rs-bin/rightsite.dll/camain?view=ca&type=caframe**to perform Documentum administrative operations. Documentum Administrator allows users with proper privileges to monitor, administer, configure, and maintain Documentum Docbases and federations located throughout the company from one system running a Web browser. This application is used “out of the box” and features no customizations.

#### Documentum RightSite Server Administrator

Documentum's RightSite Administrator allows a user to manage RightSite from a central location, and is installed with RightSite. RightSite Administrator is used in conjunction with Documentum Administrator to configure and monitor RightSite. RightSite Administrator allows user to:

* Start or stop the Virtual Session Manager (VSM).
* Reset or add configuration variables.
* Reset or add environment variables.
* View or add anonymous map user information.
* View a list of active processes.
* View or kill all active anonymous or named sessions.
* View or flush the site cache on the RightSite server.

### EDMS Implementation and Architecture

Due to the Documentum’s architectural limitation requiring the Intranet Client application and Anonymous Foundation on two different boxes, the EDMS System uses RightSite on two independent web servers. Each of the web servers is installed with NT4.0 Service Pack 6a and IIS 4.0 Service Pack 3. The anonymous foundation serves all of the EDMS custom applications, which are built to get content only from the e-Content Server.

#### RightSite Server with Intranet Client

When user accesses this RightSite server from an Internet Explorer browser version 5.5 or less, the request is passed to the HTTP server on this machine. The HTTP server identifies the request and passes the request along to RightSite Server. As the Intranet Client application and RightSite server exist on the same machine, the client request is processed using Documentum’s built-in technology and the results of the request are displayed to the user in the IE browser.

#### RightSite Server with Anonymous Mapping

This server is configured to receive requests from anonymous (guest) users. The advantage of anonymous foundation is that a user can access the server from the browser without logging into the system. When a user accesses a particular document from via a web browser, RightSite authenticates the user with the anonymous account and the request is processed. This functionality works for all the documents on which “World” has “browse” access or higher.

RightSite challenges the user with a login prompt if they attempt to access a document for which they do not have “read” access or higher. At this point the user has to authenticate using a named account, and that particular named account must have “read” access on the requested document. If both the conditions are satisfied, then the user is presented with the content of the original request.

## Functional Summary

There are twenty major functional areas of the EDMS System. Some of these functional areas, however, are not utilized via the web interface.

# Validation Planning

## Validation Strategy

The RightSite Upgrade will be prospectively validated in accordance with all applicable regulations and policies noted in Section 5.1 of this document.

The validation effort will not inspect and test every aspect of the computer system. Validation work will focus on only those functions and requirements explicitly stated in Section 5.2 of this document. Requirements will be gathered from the users of EDMS. A Risk Analysis will be performed and Detailed Design will be developed based on the scope of the Requirements and Assessment. A Validation Protocol will be executed to verify and test the Installation, Operation and Performance of the system during and following the RightSite Upgrade. A Validation Summary Report will be generated to summarize the results of the execution and to serve as the official user-acceptance document.

## Roles and Responsibilities

### Roles

The Validation Team consists of the following people performing the following roles:

| **Name** | **Role** |
| --- | --- |
| Wendy Portex | EDMS System Owner |
| Mary Hedrick, IMOC | User Representative, Tester |
| Sidney Yang | IS Project Manager |
| Jeff Conte, RIS | IS Management |
| Chris Hardwick, RIS | IS Management |
| Surya Singh | Lead RightSite Developer, Tester |
| George Anderson | QA Representative |
| Theo Hawthorne | Validation Consultant, Tester |
| TBD | Additional Testers |

### Responsibilities

#### Validation Team

The entire Validation Team is responsible for:

* Ensuring that the validation team adheres to applicable regulatory, policy and procedural requirements, and this validation plan.
* Reviewing and addressing deviations that arise during the validation process.
* Providing input into, and reviewing or approving validation documents.

#### EDMS System Owner

#### User Representative

In addition to the responsibilities associated with being a member of the Validation Team, the User Representatives is responsible for:

* Providing an end-user perspective on interface requirements, design decisions and issue resolution discussions.
* Ensuring user business processes are well defined and documented and are consistent with the use of the EDMS functionality.
* Defining the functional requirements.
* Approving, at a minimum, the Requirements Document, Validation Plan, IOPQ Protocol and Validation Summary.
* Making the final decision on the release of the interface into production.
* Ensuring that appropriate resources are available for the planning and execution of the PQ testing.

#### IS Project Manager

In addition to the responsibilities associated with being a member of the Validation Team, the IS Project Manager is responsible for:

* Ensuring that the validation team meets project plan target dates.
* Ensuring that appropriate resources are available for the design, development, test and rollout of the system.
* Managing the project scope of software development.
* Resolving project issues in a timely manner.

#### IS Management

#### Lead RightSite Developer

#### QA Representative

In addition to the responsibilities associated with being a member of the Validation Team, the QA Representatives are responsible for:

* Providing input regarding applicable compliance issues.
* Ensuring that the requirements described in the Functional Requirements Document comply with applicable regulatory and Acme policies, as identified and addressed in this document.

#### Tester

In addition to the responsibilities associated with being a member of the Validation Team, the Testers are responsible for:

* Providing sufficient knowledge of the EDMS System and Documentum in general to execute procedure steps written for a knowledgeable user.
* Executing the Validation Protocol according to the written test procedures and capturing the results of the tests in the test scripts.
* Generating documented evidence of test results in the form of screen captures, logs or other documentation that substantiates actual results of test steps.
* Capturing any deviations resulting from the execution of test procedures in the Validation Protocol.

## Validation Sequence of Events

The following information is an overview of events for completion of this validation effort. These events are to occur in the order in which they are listed below:

* Validation Plan authored and approved
* Detail Functional Requirements authored and approved
* Detailed Design authored and approved
* Validation Protocol authored and approved
* Traceability Matrix authored and approved
* IQ Protocol Section executed
* IQ Protocol Section deviations reviewed and resolved
* OQ Protocol Section executed
* OQ Protocol Section deviations reviewed and resolved
* PQ Protocol Section executed
* PQ Protocol Section deviations reviewed and resolved
* Validation Summary Report authored and approved
* System Released for full Production use

## Validation Deliverables

### Requirements Document

The Functional Requirements document describes what functionality the interface needs to implement. This document defines in specific terms the minimum set of functionality that the system must support and is the reference document against which test scripts will be developed. As the scope of this validation is limited to the RightSite interface of the EDMS System, this requirements document contains only requirements applicable to the RightSite interface.

### Design Document

The Detailed Design document provides the detailed requirements for the design, structure, and configuration of the application components and will be created based on the Functional Requirements document. The document must provide sufficient detail to build or buy the application and components, including necessary hardware, software and configuration.

This document describes how requirements will be implemented through configuration and customization. The design must include the function’s objective, a quantitative statement of performance, accuracy, throughput and how custom modules will be integrated with the existing applications and each other. This includes any required inputs and outputs as well as processing of applicable business rules and process flows.

### Validation Protocol

Validation Protocols are the documents that drive the functional and performance testing of the application in its intended environment. Tests will be designed to provide documented evidence that the system has been installed properly and that requirements have been met. Pre-determined test acceptance criteria will be based on the requirements and design documents and will be approved before the execution of the protocols.

All testing must be executed formally from approved protocols using approved test scripts. Testing will be done according to a written testing procedure and the executed results will be verified against the acceptance criteria. Deviations will be resolved according to the established procedure for failure resolution. If the acceptance criteria are not met, a deviation log entry will be completed and the approved corrective action followed as detailed in the protocol. The test results will be approved as acceptable or rejected pending adequate remedial actions that will be taken and documented.

This validation effort will follow one Validation Protocol that incorporates aspects of the IQ, OQ and PQ. This Protocol is divided into three primary sections corresponding to the respective sections.

#### IQ Protocol Section

The IQ Protocol Section documents the planned validation efforts to provide verification that the system is installed and configured properly prior to testing and system rollout. This provides documentation that the components adhere to appropriate design intentions, including all applicable vendor recommendations.

As this validation is limited to the RightSite Upgrade of the EDMS System, only installation and configuration of the RightSite servers and software will be validated. This includes any external interfaces that use RightSite to access EDMS.

#### OQ Protocol Section

The OQ Protocol Section documents the planned validation efforts to provide verification that the system is operating according to specified design after installation. This section will focus on the software functionality and will be executed after successful completion of the IQ Protocol Section of the document. Each critical software component will be tested to verify that it performs in accordance with the Functional Requirements and Detailed Design. This includes:

* Testing all critical functions and designs as defined
* Testing all screens using valid and invalid data entry
* Exercising all alarms and error messages
* Testing data integrity
* Challenging security access
* Testing component inputs
* Observing all outputs
* Exercising each expected decision path.

#### PQ Protocol Section

The PQ Protocol documents the planned validation efforts to provide verification that the system performs properly under actual conditions of use by trained end-users. The PQ test protocol will be based on intended user operations in production situations. The PQ will be executed after successful completion of the OQ Protocol Section of the document.

### Traceability Matrix

The Traceability Matrix will show the relationship between requirements, design elements and test protocols defined in the Functional Requirements, Detailed Design and IOPQ Protocol. All protocol sections and test scripts will be traceable to the user requirements for the system using this matrix. It will be used to confirm that all requirements have been incorporated into the design and are tested. The traceability matrix may also be used during subsequent change control evaluation to identify the impact of changes to the system and the validation documents.

### Validation Summary Report

A final Validation Summary Report will be prepared after completion of the Validation Protocol. This report will contain a summary description of all testing results generated during the execution of the IQ, OQ and PQ portions of the Validation Protocol and a description and resolution of any deviations. This report will state conclusions about the acceptability of the protocol results and confirm that all validation activities have been completed.

# Acceptance Criteria

## User Acceptance

Completion of and subsequent approval of the Validation Summary Report shall constitute official user acceptance of the system. This report will be approved prior to full use of the system in production. It will represent that all validation requirements have been met, all deviations and failures have been successfully resolved and that the user accepts the system.

## Documentation Management

All documents generated, as a result of this qualification effort will be archived according to Quality Assurance procedures.